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MAY - 4 2007

In re Application of Conrad :  
Serial No.: 10/667,126 :  
Filed: 19 September 2003 : PETITION DECISION  
Attorney Docket No.: AMBI:086US :  
:

This is in response to the petition under 37 CFR 1.144, filed 5 April 2007, requesting reconsideration of the restriction requirement.

## BACKGROUND

A review of the file history shows that this application was filed on 19 September 2003, under 35 U.S.C. 111(a). The examiner mailed to applicants on 28 September 2006, a restriction requirement in which the original claims 1-53 were divided into 6 groups. Five of the groups are directed to methods while one of the groups is directed to a product, as follows:

### **Restriction to one of the following inventions is required under 35 U.S.C. 121:**

- I. **Claims 1-41, drawn to a method for isolating small RNA molecules, classified in class 536, subclass 25.4.**
- II. **Claims 42-45, drawn to a method for isolating miRNA or siRNA, classified in class 536, subclass 25.4.**
- III. **Claims 46 and 47, drawn to a method for isolating miRNA, classified in class 536, subclass 25.4.**

- IV. Claim 48, drawn to a method for isolating small RNA, classified in class 536, subclass 25.4.**
- V. Claim 49, drawn to a kit for isolating small RNA, classified in class 536, subclass 25.4.**
- VI. Claims 50-53, drawn to a method for isolating small RNA, classified in class 536, subclass 25.4.**

On 28 November 2006, Applicants elected Group II, claims 42-45 with traverse.

On 5 April 2004, the examiner mailed an Office action which considered the traversal and rejoined Group III with elected invention of Group II. The restriction requirement among Groups I, (II/III), IV, V and VI was made FINAL. Claims 1-41, 48-53 and 56-57 were withdrawn from consideration. Claims 42-47 and 52-55 were examined on the merits. Claim 45 was rejected under 35 USC 112, second paragraph for indefiniteness. Claims 42-47 and 52-55 were rejected under 35 USC 103(a) as being unpatentable over Laugharn, in view of RNA STAT-60 Reagent, Moss and Ambros.

Applicants filed a response and a claim amendment on 5 April 2007. Applicants also filed this petition on 5 April 2007, requesting reconsideration of restriction requirement and rejoinder of Groups I, II, III, IV and VI.

## **DISCUSSION**

The file history and petition have been carefully considered.

All of the process groups are directed to the isolation of RNA molecules. As such, the processes are related in terms of effect- they all result in isolated RNA molecules and as such, cannot be considered to be independent inventions.

Moreover, all of the process claims require the same three active steps of adding an alcohol to a sample containing RNA, applying the sample to a support, eluting the RNA molecules from the support.

The Examiner had reasoned that the process claims were distinct because the independent claims of each group require limitations not required for the independent claims of the other groups. However, when determining whether claimed inventions are distinct, it is necessary to look at both the independent and dependent claims, particularly when analyzing process inventions. The open claim language "comprising" that precedes the active steps allows for additional active steps recited in the dependent claims, which need to be considered.

In this application, the process claims have been drafted using a combination of broad and narrow limitations to describe the same invention. For example, Claim 1 does not specify that

the RNA must be siRNA or miRNA. The independent claim 42 of Group II limits the process to the isolation to miRNA or siRNA; however dependent claim 2 of Group I provides a limitation that the RNA is an siRNA or miRNA. Similarly, independent claim 1 of Group I requires lysing cells to produce a cell lysate. Independent claim 42 of Group II is silent as to whether the sample contains lysed cells; however dependent claim 43 of Group II specifically requires a cell lysate. A similar analysis of the independent claims and the dependent limitations would further support the finding that the processes of Groups I, II, III, IV and VI are not distinct.

MPEP 803 sets forth the two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.06, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(j)); and
- (B) There would be a serious burden on the examiner if restriction is not required (see MPEP § 803.02, § 808, and § 808.02).

In this particular instance, the Office cannot maintain showing a showing of independence or distinction with regard to the process inventions of Groups I, II, III, IV and VI.

## **DECISION**

The petition is **GRANTED** for the reasons set forth above.

The restriction requirement made between Groups I, II, III, IV and VI has been withdrawn. Process of Groups I, IV and VI will be rejoined for examination with the Groups II/III for the reasons set forth above.

**The application will be forwarded to the examiner for further action consistent with this decision and to consider the papers filed 5 April 2007.**

Should there be any questions about this decision, please contact Quality Assurance Specialist/Program Manager Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.



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